

## Food and Drug Administration, HHS

## § 866.5200

antitrypsin deficiency has been associated with pulmonary emphysema.

(b) *Classification*. Class II (performance standards).

### § 866.5150 Bence-Jones proteins immunological test system.

(a) *Identification*. A Bence-Jones proteins immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the Bence-Jones proteins in urine and plasma. Immunoglobulin molecules normally consist of pairs of polypeptide chains (subunits) of unequal size (light chains and heavy chains) bound together by several disulfide bridges. In some cancerous conditions, there is a proliferation of one plasma cell (antibody-producing cell) with excess production of light chains of one specific kind (monoclonal light chains). These free homogeneous light chains not associated with an immunoglobulin molecule can be found in urine and plasma, and have been called Bence-Jones proteins. Measurement of Bence-Jones proteins and determination that they are monoclonal aid in the diagnosis of multiple myeloma (malignant proliferation of plasma cells), Waldenstrom's macroglobulinemia (increased production of large immunoglobulins by spleen and bone marrow cells), leukemia (cancer of the blood-forming organs), and lymphoma (cancer of the lymphoid tissue).

(b) *Classification*. Class II (performance standards).

### § 866.5160 Beta-globulin immunological test system.

(a) *Identification*. A beta-globulin immunological test system is a device that consists of reagents used to measure by immunochemical techniques beta globulins (serum protein) in serum and other body fluids. Beta-globulin proteins include beta-lipoprotein, transferrin, glycoproteins, and complement, and are rarely associated with specific pathologic disorders.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in

subpart E of part 807 of this chapter subject to § 866.9.

[47 FR 50823, Nov. 9, 1982, as amended at 65 FR 2312, Jan. 14, 2000]

### § 866.5170 Breast milk immunological test system.

(a) *Identification*. A breast milk immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the breast milk proteins.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 866.9.

[47 FR 50823, Nov. 9, 1982, as amended at 59 FR 63007, Dec. 7, 1994; 66 FR 38793, July 25, 2001]

### § 866.5180 Fecal calprotectin immunological test system.

(a) *Identification*. A fecal calprotectin immunological test system is an *in vitro* diagnostic device that consists of reagents used to quantitatively measure, by immunochemical techniques, fecal calprotectin in human stool specimens. The device is intended for *in vitro* diagnostic use as an aid in the diagnosis of inflammatory bowel diseases (IBD), specifically Crohn's disease and ulcerative colitis, and as an aid in differentiation of IBD from irritable bowel syndrome.

(b) *Classification*. Class II (special controls). The special control for these devices is FDA's guidance document entitled "Class II Special Controls Guidance Document: Fecal Calprotectin Immunological Test Systems." For the availability of this guidance document, see § 866.1(e).

[71 FR 42598, July 27, 2006]

### § 866.5200 Carbonic anhydrase B and C immunological test system.

(a) *Identification*. A carbonic anhydrase B and C immunological test system is a device that consists of the reagents used to measure by immunochemical techniques specific carbonic anhydrase protein molecules in serum and other body fluids. Measurements of carbonic anhydrase B and C aid in the diagnosis of abnormal hemoglobin metabolism.

## § 866.5210

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 866.9.

[47 FR 50823, Nov. 9, 1982, as amended at 65 FR 2312, Jan. 14, 2000]

### § 866.5210 Ceruloplasmin immunological test system.

(a) *Identification*. A ceruloplasmin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the ceruloplasmin (copper-transporting serum protein) in serum, other body fluids, or tissues. Measurements of ceruloplasmin aid in the diagnosis of copper metabolism disorders.

(b) *Classification*. Class II (performance standards).

### § 866.5220 Cohn fraction II immunological test system.

(a) *Identification*. A Cohn fraction II immunological test system is a device that consists of the reagents that contain or are used to measure that fraction of plasma containing protein gamma globulins, predominantly of the IgG class. The device may be used as a coprecipitant in radioimmunoassay methods, as raw material for the purification of IgG subclasses, and to reduce nonspecific adsorption of plasma proteins in immunoassay techniques. Measurement of these proteins aids in the diagnosis of any disease concerned with abnormal levels of IgG gamma globulins such as agammaglobulinemia or multiple myeloma.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 866.9.

[47 FR 50823, Nov. 9, 1982, as amended at 59 FR 63007, Dec. 7, 1994; 66 FR 38793, July 25, 2001]

### § 866.5230 Colostrum immunological test system.

(a) *Identification*. A colostrum immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the specific proteins in colostrum. Colostrum is a substance excreted by the mammary glands during

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pregnancy and until production of breast milk begins 1 to 5 days after childbirth.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 866.9.

[47 FR 50823, Nov. 9, 1982, as amended at 59 FR 63007, Dec. 7, 1994; 66 FR 38793, July 25, 2001]

### § 866.5240 Complement components immunological test system.

(a) *Identification*. A complement components immunological test system is a device that consists of the reagents used to measure by immunochemical techniques complement components C<sub>1q</sub>, C<sub>1r</sub>, C<sub>1s</sub>, C<sub>2</sub>, C<sub>3</sub>, C<sub>4</sub>, C<sub>5</sub>, C<sub>6</sub>, C<sub>7</sub>, C<sub>8</sub>, and C<sub>9</sub>, in serum, other body fluids, and tissues. Complement is a group of serum proteins which destroy infectious agents. Measurements of these proteins aids in the diagnosis of immunologic disorders, especially those associated with deficiencies of complement components.

(b) *Classification*. Class II (performance standards).

[47 FR 50823, Nov. 9, 1982, as amended at 53 FR 11253, Apr. 6, 1988]

### § 866.5250 Complement C<sub>2</sub> inhibitor (inactivator) immunological test system.

(a) *Identification*. A complement C<sub>2</sub> inhibitor (inactivator) immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the complement C<sub>2</sub> inhibitor (a plasma protein) in serum. Complement C<sub>2</sub> inhibitor occurs normally in plasma and blocks the action of the C<sub>2</sub> component of complement (a group of serum proteins which destroy infectious agents). Measurement of complement C<sub>2</sub> inhibitor aids in the diagnosis of hereditary angioneurotic edema (increased blood vessel permeability causing swelling of tissues) and a rare form of angioedema associated with lymphoma (lymph node cancer).

(b) *Classification*. Class II (performance standards).